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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,184	07/16/2003	Eckhard Alt	ACR/050	2237

53164 7590 04/21/2006

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EXAMINER	
SZMAL, BRIAN SCOTT	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,184	ALT, ECKHARD	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *23 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Claims 23 and 24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 10, 2006.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 6 and 8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23 and 24 of U.S. Patent No. 6,829,503 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are written in a broader language than the issued claims.

4. Claims 9, 10, 12 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10 and 11 of U.S. Patent No. 6,829,503 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are written in a broader language than the issued claims.

5. Claims 11 and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 6,829,503 B2 in view of Turcott (6,600,949 B1). Alt fails to disclose the use of an accelerometer and telemetry means. Turcott discloses a means for monitoring heart failure and further discloses the use of an accelerometer and telemetry means. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the use of an accelerometer and a telemetry means, as per the teachings of Turcott, since it would provide an additional means of measuring physiological parameters as well as relaying the acquired data to a remote location for further processing or review by a physician.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 17 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In line 4, "electrodes contacting subcutaneous tissue"

constitutes non-statutory subject matter because the electrodes are not "adapted for" contacting the tissue.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-5, 9, 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt (4,884,576).

Alt discloses a rate responsive pacemaker and method and further discloses performing ongoing measurements of changes in local impedance of a portion of the patient's body between at least two electrodes on the exterior of the implanted device, the changes representing ventilation of the patient, including measuring the patient's respiratory rate and respiratory amplitude; controlling the rate of a rate adaptive cardiac pacemaker, using the patient's ventilation represented by the measured changes in local impedance; detecting the cardiopulmonary status of the patient, using the patient's ventilation represented by the measured changes in local impedance; deriving a signal from the measured changes in local impedance that reflects congestion in heart failure

patients; deriving both the patient's ventilation and DC impedance from the measured changes in local impedance, from which to detect an early stage of lung congestion of the patient; a circuit module coupled to plural surface electrodes of the device arranged and adapted, when the device is implanted, for contacting tissue in a portion of the patient's body generally occupied by the lungs, to monitor changes in local impedance of the body portion, and to detect the patient's EKG; the circuit module utilizes at least two of the electrodes to both monitor the changes in local impedance and detect the patient's EKG; and the device is adapted to be implanted subcutaneously. See Column 5, lines 4-9, 17-20, 36-54 and 60-68; Column 6, lines 1-3, 33-47; Column 8, lines 40-42; Column 9, lines 37-39 and 54-57; Column 10, lines 35-40; and Column 11, lines 43-53. Even though Alt does not explicitly disclose the placement of the impedance measurement means, the placement of the electrodes on the lower left side of the patient is inherently disclosed due to the measurement of the impedance value, and the use of the acquired value to determine the cardiopulmonary condition.

9. Claims 6, 8 and 16-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Turcott (6,600,949 B1).

Turcott discloses a means for monitoring heart failure and further discloses subcutaneously implanting an impedance monitoring device at a location on the patient's thorax at the lower part of the lungs constituting a site where initial accumulation of fluid occurs in the lungs, and monitoring impedance changes at said location to detect pulmonary congestion; implanting a subcutaneous impedance measuring device with electrodes connected thereto, and positioning the electrodes to

measure impedance on the lower left side of the patient's lungs; a first subsystem to detect the patient's intrinsic heart activity, a second subsystem to analyze and store the intrinsic heart activity, a third subsystem to evaluate a physical activity pattern of the patient generated by a mechanical-electrical converter, a fourth subsystem to analyze and store the physical activity pattern, a fifth subsystem to measure and evaluate impedance at a local implant site of the device, and a sixth subsystem to analyze and store the impedance, and to derive from the functions of the first, second, third, fourth, fifth and sixth subsystems information representing the cardio-pulmonary status of the patient; detection apparatus responsive to the heart rate/activity pattern of the patient and the impedance between a pair of electrodes contacting subcutaneous tissue at opposite sides of a lung of the patient, for performing the evaluation, and evaluation apparatus for evaluating the trend of the heart rate/activity pattern and the impedance against one another, over a selected period of time; a housing for the device, the device having electrodes on a surface of the housing constituting the only electrodes of the device, for detecting local impedance changes therebetween and locally derived EKG after the device is implanted in the patient, and the housing incorporating a mechano-electrical converting element therein for responding to the status of physical activity of the patient; an electronic module in the housing to determine from information derived from the impedance changes, the EKG and the status of physical activity, the status of congestive heart failure of the patient; an electronic module in the housing to determine from information derived from the impedance changes, the EKG and the status of physical activity, the need for increasing or decreasing the heart rate of the patient; an

electronic module in the housing to determine from information derived from the impedance changes, the EKG and the status of physical activity, the occurrence of potentially lethal arrhythmias of the patient; and the mechano-electrical converting element is an accelerometer. See Column 8, line 55; Column 9, line 4; Column 11, lines 29-32; Column 13, lines 49-50 and 58-61; Column 14, lines 29-32 and 49-61; and Column 18, lines 45-54.

10. Claims 7 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Bardy (6,336,903 B1).

Bardy discloses a means for collecting and analyzing data to diagnose congestive heart failure and further discloses detecting the patient's intrinsic heart activity, analyzing and storing the analysis of the detected intrinsic heart activity, evaluating a pattern of the patient's intrinsic heart activity derived from said analysis, and measuring and evaluating impedance at a selected site on the patient's body, and using the impedance evaluation together with the intrinsic heart activity pattern evaluation to derive information representing the cardiopulmonary status of the patient; and an apparatus for measuring a patient's subcutaneous impedance at a location on the patient's body where the measured impedance has a linear correlation with the patient's cardiac output, and for monitoring a decrease in impedance baseline value to indicate cardiopulmonary status of the patient. See Column 5, lines 52-56 and 62-67; Column 6, lines 1-10 and 35-41; Column 9, lines 42-58; Column 11, lines 60-64; Column 12, line 25; and Column 15, lines 6-10, 15, 34, 35, 52 and 53.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt (4,884,576) as applied to claim 9 above, and further in view of Turcott (6,600,949 B1).

Alt, as discussed above, discloses a means of monitoring cardiac and respiratory parameters, but fails to disclose the circuit module includes an accelerometer within the device; the circuit module includes a patient alert function; and the circuit module includes means for telemetry communication with one or more control units external to the patient's body.

Turcott, as discussed above, discloses a means for monitoring heart failure and further discloses the circuit module includes an accelerometer within the device; the circuit module includes a patient alert function; and the circuit module includes means for telemetry communication with one or more control units external to the patient's body. See Column 8, line 55; Column 9, line 4; Column 11, lines 29-32; Column 13, lines 49-50 and 58-61; Column 14, lines 29-32 and 49-61; and Column 18, lines 45-54.

Since both Alt and Turcott disclose means for monitoring cardiopulmonary parameters, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Alt to utilize an accelerometer, an alerting means and

a telemetry means, as per the teachings of Turcott, since it would provide an additional means of measuring physiological parameters as well as relaying the acquired data to a remote location for further processing or review by a physician.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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